# KANSAS STATE BOARD OF PHARMACY MINUTES OF THE MEETING

March 6 & 7, 2007 KU School of Pharmacy Malott Hall Room 6056 Lawrence, Kansas 66615

## Tuesday, March 6, 2007

**MEMBERS PRESENT:** Max Heidrick, RPh., President; JoAnne Gilstrap, RPh., Vice President; Merlin McFarland, R.Ph., Dr. Shirley Arck, Pharm.D.; and Michael Coast, R.Ph.

**STAFF PRESENT:** Debra Billingsley, Executive Secretary; Jim Kinderknecht, RPh., Pharmacy Inspector; Carly Haynes, R.Ph., Pharmacy Inspector; Tom Frazier, R.Ph. Pharmacy Inspector; Melissa Martin, Compliance Officer; Reyne Kenton, Compliance Officer; and Randall Forbes, General Counsel.

**OTHERS PRESENT:** See attached listing.

**MEETING CALLED TO ORDER:** Max Heidrick called the meeting to order at 9:45 a.m.

## WELCOME TO DEAN OF KU SCHOOL OF PHARMACY

The Board thanked Dean Ken Audus for hosting the meeting at the KU School of Pharmacy.

## WELCOME AND INTRODUCTION OF NEW PHARMACY INSPECTOR

The Board was introduced to new pharmacy inspector, Carly Haynes, R.Ph. Carly is over Southeast Kansas and the Wichita area and is a welcome addition to the Board of Pharmacy staff.

**APPROVAL OF AGENDA**. A motion was made and seconded to approve an amended agenda. The agenda was amended to add discussion of K.A.R. 68-7-14 regarding labels; the Unused Medications Bill; HB 2531 regarding Wholesale Distributor Licenses; Telepharmacy regulations and HB 2530 regarding Consumer Protection laws; Dighton Drug Case No. 06-74 and Margaret Cameron, Pharmacy Technician Application review. (Coast/Gilstrap) Motion carried 4-0.

**APPROVAL OF DECEMBER BOARD MINUTES** A motion was made and seconded to approve the December 2006 minutes. (Arck/Coast). Motion carried 4-0.

# ADMINISTRATIVE PROCEEDINGS JAMES WHERMAN, R.Ph. Case No. 06-95

The Respondent appeared in person and through his counsel, Steve Schwarm. The Board appeared through its counsel, Randall Forbes. John Childers, LMSW and Executive Director of HAPN was also present. The proposed discipline was a Stipulation which provided for the standard CIPP requirements. A motion was made and seconded to go into executive session to review confidential information until 9:55 a.m. (Coast/McFarland). Motion carried 3-0. The Board reconvened at 9:55 a.m. A motion was made and seconded to accept the Stipulation. (Arck/Coast). Motion carried 3-0.

# JAMES CAVE, R.Ph. Case No. 06-61

The Respondent appeared in person. The Board appeared through its counsel Randall Forbes. John Childers, LMSW and Executive Director of HAPN was also present. The proposed discipline was a Stipulation which provided for the standard CIPP requirements. A motion was made and seconded to go into executive session to review confidential information until 10:10 a.m. (McFarland/Coast). Motion carried 3-0. The Board reconvened at 10:10 a.m.. A motion was made and seconded to accept the Stipulation. (McFarland/Coast). Motion carried 3-0.

# RAYMOND PERRENOUD, R.Ph. Case No. 06-67

The Respondent appeared in person. The Board appeared through its counsel Randall Forbes. John Childers, LMSW and Executive Director of HAPN was also present. The proposed discipline was a Stipulation which provided for the standard CIPP requirements. A motion was made and seconded to go into executive session to review confidential information until 10:25 a.m. (Coast/McFarland). Motion carried 3-0. The Board reconvened at 10:25 a.m. A motion was made and seconded to accept the Stipulation. (McFarland/Arck). Motion carried 3-0. The Respondent was directed to notify his employer in writing, with a copy to the Board, that he has a contract with CIPP.

# DISCUSSION REGARDING HOUSE BILL 2530

Steve Schwarm advised the Board that Kansas Medical Society had proposed an amendment that would exempt physicians and other health care providers from Consumer Protection statutes. This was the result of a recent court decision whereby the Court deemed professional medical services to be under the Consumer Protection Statutes. The amendment would not exempt issues related to billing or other business practices but would exempt professional services. Professional services were not defined in the bill and there is no definition of healthcare provider. KPhA Executive Director, Mike Larkin, advised the Board that they had been following this legislation.

# NOEL MCBRIDE, R.Ph. Case No. 06-45

The Respondent appeared in person. The Board appeared through its counsel Randall Forbes. John Childers, LMSW and Executive Director of HAPN was also present. The Respondent made a request for modification of the Stipulation and Final Order that was entered in September 2006. Specifically, the Respondent requested that the restriction preventing him from dispensing be removed. A motion was made and seconded to adjourn into an executive session to review confidential information until 10:50 a.m.

(McFarland/Coast). Motion carried 4-0. The Board reconvened at 10:50 a.m. The Board recommended that the Respondent work with HAPN regarding providing additional information to the Board. No formal action was taken regarding the Stipulation.

**ADJOURN** The Board took a ten minute recess.

## ALFRED J. FLASCHEL, JR. Case No. 06-100

The Respondent appeared in person. The Board was represented by its attorney, Randall Forbes. The matter was before the Board on a Request for Hearing related to the Summary Order of Revocation issued against the Respondent's pharmacy technician registration. Testimony was received from Greg Leiker the CVS Regional Loss Prevention Manager and from the Respondent. Exhibits were also offered. A motion was made and seconded to adjourn into executive session for the purpose of deliberations until 11:40 a.m. (McFarland/Coast). Motion carried 3-0. The Board reconvened at 11:40 a.m. A motion was made and seconded to uphold the Agency Order of Revocation. (Coast/Arck). Motion carried 3-0.

## DIGHTON DRUG Case No. 06-74

The Respondent did not appear. The Board was represented by its attorney, Randall Forbes. The Board was provided with a Stipulation and Final Agency Order. The proposed discipline was a fine of \$500 for failing to prepare an incident report regarding a label error and misfill; a fine of \$500 for failing to prepare an incident report regarding the labeling error of a prescription; a fine of \$500 for failing to prepare an incident report regarding a label error and misfill; and a fine of \$500 for failing to prepare an incident report regarding a misfill. The Board requested that the Respondent provide information as to how these errors will be prevented in the future as it relates to labeling, filling, and reporting of incidents. A motion was made and seconded to accept the Stipulation and Final Agency Order (McFarland/Arck). Motion carried 3-0.

# REPORT FROM HAPN

John Childers, LMSW, the Executive Director of HAPN visited with the Board regarding his new position with CIPP. The Board welcomed John to the meeting and advised him that his attendance at the Board meetings were helpful to the Board and to the Respondents.

**ADJOURN:** The Board adjourned for lunch at noon.

**RECONVENE:** The Board reconvened at 12:50 p.m.

# LEGISLATIVE UPDATE

The Honorable Don Hill, R.Ph. appeared before the Board and gave a short update on legislative matters. HB 2097 regarding immunizations was amended and passed out of the House Health Committee. It provides that pharmacy students who have been trained and certified to administer immunizations may do so under the direct supervision of a pharmacist. It also provides that current CPR certification be maintained. The bill has not made it out of the full House. HB 2096 related to Board meetings has passed through

the House and the Senate Health Committee. SB 270 requires the Board appoint someone to a task force regarding prescription drug monitoring and Sudafed monitoring. The Board discussed appointing Barry Sarvis, R.Ph. and Shirley Arck, Pharm.D. was asked to contact him.

## CUSTOM MEDICATIONS CASE NO. 07-03

The Respondent, Lee Ori, Pharm.D. appeared in person and with his counsel, Ed Richter. The Board was represented by it attorney, Randall Forbes. The matter was before the Board on a pharmacy license application. The Board reviewed the application as it related to compounding, manufacturing, shared services, and FDA statutes and regulations. The Board took the matter under advisement until such time as they could get a legal opinion from counsel.

## PHARMACY TECHNICIAN APPLICATION REVIEW

## DEIDRE KALEEN ELROD

The Respondent appeared in person. The Board was represented by its attorney, Randall Forbes. The matter was before the Board on a pharmacy technician application. The Board approved the applicant for registration as a pharmacy technician.

## **MELISSA MATHISON**

The Respondent appeared in person. The Board was represented by its attorney, Randall Forbes. The matter was before the Board on a pharmacy technician application. The Board approved the applicant for registration as a pharmacy technician.

## JUSTIN JOHN STINE

The Board deferred action on the application until such time as the applicant appears before the Board.

## JAIME NICOLE BRADY

The Respondent appeared in person. The Board was represented by its attorney, Randall Forbes. The matter was before the Board on a pharmacy technician application. The Board approved the applicant for registration as a pharmacy technician.

## MARGARET CAMERON

The Respondent appeared in person. The Board was represented by its attorney, Randall Forbes. The matter was before the Board on a pharmacy technician application. The Board approved the applicant for registration as a pharmacy technician.

## **EXECUTIVE SESSION**

A motion was made and seconded to go into Executive Session to discuss staff personnel issues until 2:00 p.m. (Arck/Coast) Motion carried 4-0. Board reconvened at 2:00 p.m.

## INVESTIGATIVE REPORT

Presented by JoAnne Gilstrap, Vice President /Investigative Member The Board reviewed closed cases.

#### **VAWD INSPECTIONS**

The Board discussed the report received from Melissa Martin regarding the VAWD inspection that was conducted at Heritage Labs in Olathe. The inspection was conducted by an independent inspector hired by NABP and Melissa was able to observe the inspection process. The Board discussed the process as it is related to HB 2531 regarding licensure of wholesale distributors. The Board requested that Board staff provide additional information regarding the process used by NABP.

#### PLAN B SURVEY

The Board received a request from Julie Schrack and Erin Stump. They are both Master of PA students at Wichita State University. They want to conduct a research study regarding pharmacist's knowledge, attitudes, and beliefs regarding OTC emergency contraception. They requested that the Board put something in their newsletter asking pharmacists to voluntary go to a website in order to take a survey. The Board reviewed the questions and the request. They denied the request and suggested that the individuals go through KPhA.

#### EDUCATION OF TECHNICIANS

The Board reviewed and discussed information related to Ohio Senator Tim Grendell's plan to introduce a bill in Ohio that would require pharmacy technicians to complete a two-year training program or internship, pass a state or national exam, and be licensed through the Ohio State Board of Pharmacy. The proposal would set the technician ratio at 3 to 1. US Representative Steve LaTourette is reportedly working on a bill that would establish federal standards for pharmacy technician training and registration. These bills were prompted after the death of a 2-year old when a pharmacy technician incorrectly prepared the child's intravenous chemotherapy treatment for cancer.

#### MEETING WITH THE ATTORNEY GENERAL

Board President,Max Heidrick,R.Ph, Debra Billingsley, and Randy Forbes met with Attorney General Paul Morrison on February 14, 2007. They were invited along with other state agencies to discuss whether they were using the Attorney General's Office for general counsel or litigation issues. The agencies were permitted to express any concerns they had with the work product from the A.G.'s office. Attorney General Morrison stated that he would work with each Board and try to resolve any problems that they may have had with attorneys assigned to their Board.

# POLICY REGARDING REQUESTS FROM THE PRESS

The Board reviewed suggestions from communication experts regarding how to deal with requests from the press. The Board agreed that they should have a written policy that states that any case that is under investigation or has a potential for becoming an investigation should not be commented on. It would be inappropriate to comment on a case prior to the investigation or prior to a hearing so that the licensee receives due process of the law. The Board staff will work toward putting together a policy that can be approved at a later date.

## COMPOUNDING DRUG TESTING

The Board reviewed information from the Missouri Board regarding their testing of drug preparations compounded by pharmacies. All preparations are tested for potency and if applicable, sterility and endotoxin. The Board requested that Board staff contact Missouri to determine what their costs are associated with their testing and how it was funded.

## HB 2531 WHOLESALE DISTRIBUTOR LICENSING

The Board reviewed proposed amendments to HB 2531 that were suggested by HDMA and by NACDS. The Board will determine whether to accept the amendments and will provide a balloon amendment next week to the legislature. Testimony was taken regarding this bill in the House Health Committee and there were no opponents.

## UNUSED MEDICATION ACT

The Board was provided with a copy of the Unused Medication Act that has been filed conceptually in Appropriations. The Board reviewed the bill and had some questions as it related to K.S.A. 65-1648. The Board believes that there could be some conflict with current statute and the proposed statute regarding Board authority and oversight. The Board staff will provide these comments to the Revisor's Office.

## APPROVAL OF 50 YEAR CERTIFICATES

A motion was made and seconded to approve the 50 year certificates for pharmacists that had a continuous (Gilstrap/Arck). Motion carried 4-0.

## APPROVAL OF NEW LICENSES AND REGISTRATIONS

A motion was made and seconded to approve the new pharmacist's licenses and pharmacy registrations. (Arck/McFarland) Motion carried 4-0.

#### SPECIAL PRESENTATION TO HOWARD PAUL

A special presentation was made to Howard Paul for his service and leadership to the profession of pharmacy. Howard served as the public member of the Board from April 2003 until February 2007. The Board acknowledged his volunteer service.

## **ADJOURNMENT:**

A motion was made and seconded to adjourn the meeting until 9:00 a.m. Wednesday, March 7, 2007. (Arck/Coast). Motion carried 4-0.

# Wednesday, March 7, 2007

**MEMBERS PRESENT:** Max Heidrick, R.Ph., President; JoAnne Gilstrap, R.Ph., Vice-President Merlin McFarland, R.Ph; Dr. Shirley Arck, R.Ph., Michael Coast, R.Ph.; and Nancy Kirk, public member.

**STAFF PRESENT:** Debra Billingsley, Executive Director; Jim Kinderknecht, R.Ph., Pharmacy Inspector; Carly Haynes, R.Ph., Pharmacy Inspector; Tom Frazier, R.Ph.,

Pharmacy Inspector; Reyne Kenton, Compliance Officer; Melissa Martin, Compliance Officer; and Randall Forbes, General Counsel.

**OTHERS PRESENT:** See Attached listing

## **MEETING CALLED TO ORDER:**

Max Heidrick called the meeting to order at 9:00 a.m.

## WELCOME TO NEW BOARD MEMBER

The Board welcomed new Board member, Nancy Kirk. Ms. Kirk is replacing Howard Paul as the public member on the Board.

**ADJOURNMENT:** Mr. Heidrick adjourned the meeting for public hearing at 9:00 a.m.

#### PUBLIC HEARING:

## K.A.R. 68-5-16 RATIO OF PHARMACY TECHNICIANS TO PHARMACISTS.

The Board office received correspondence from NACDS expressing concerns with the regulation as it related to the national certification of technicians. The letter was provided to the Board. Becca Baugher, Pharm.D.ANP of CardinalHealth requested clarification regarding the intent of the regulation as it related to training programs and whether the Board had approved any other programs other than PTCB. The Board advised that PTCB and ICPT had both been approved by the Board. The Board heard comments from Jody Lewis, Pharmacy Supervisor for CVS related to the issue of requiring two technicians to maintain national certification in order for the ratio to be raised. Ms. Lewis stated that the regulation was more stringent than the current regulation and would put a burden on pharmacies with the requirement that two individuals be nationally certified. There is already a shortage of help and the regulation amendment as written places a burden on retail pharmacies. The Board discussed this issue and determined that the Board had compromised by requiring two pharmacy technicians be nationally certified in order to raise the ratio because there were some board members who felt that all three should be certified.

# MEETING CALLED TO ORDER

President Heidrick, R.Ph. called the meeting back to regular session.

A motion was made and seconded to adopt regulation KAR 68-5-16. (McFarland/Arck). A roll call vote was taken as follows: Nancy Kirk – Yes; Shirley Arck, Pharm.D. – Yes; JoAnne Gilstrap, R.Ph., – Yes; Merlin McFarland. R.Ph., – Yes; Mike Coast, R.Ph. – Yes. Regulation passed unanimously.

## **ADJOURNMENT**

President Heidrick, R.Ph. adjourned the meeting for public hearing at 9:10 a.m.

#### **PUBLIC HEARING**

#### **K.A.R. 68-5-16 ORDER FORMS.**

The Board staff provided the Board with a letter from the Joint Committee on Administrative Rules and Regulations. There was no other communication sent to the Board office and there were no comments from the public.

## MEETING CALLED TO ORDER.

President Heidrick, R.Ph. called the meeting back to regular session.

A motion was made and seconded to adopt K.A.R. 68-20-17 regarding Order Forms (Coast/McFarland). A roll call votes was taken as follows: Nancy Kirk – Yes; Shirley Arck, Pharm.D. – Yes; JoAnne Gilstrap, R.Ph. – Yes; Merlin McFarland, R.Ph. – Yes; Mike Coast, R.Ph. – Yes. Regulation passed unanimously

## **UPDATE ON REGULATIONS:**

## TELEPHARMACY REGULATION

The Board reviewed the draft regarding telepharmacy regulations. The Board discussed deleting a mileage requirement and placing the burden on the applicant to show that the area is underserved. If the area is pharmaceutically underserved and there is no impact on surrounding bricks and mortar pharmacies the Board would be able to approve. The Board requested additional language so that it is clear that there has to be a real time participant on both ends. The Board also wanted clarification that this would be for instate participants only and that it should not cross state lines due to difficulties in the Board having jurisdiction and control. The Board deemed it a necessity that the Board inspectors have access to both the bricks and mortar pharmacy and the telepharmacy.

**K.A.R. 68-20-23 Limitation on Controlled Substances.** The regulation has been sent for review but has not been returned to the Board for public hearing.

**K.A.R. 68-7-11 & 68-7-12 Requiring Inventory by PIC.** The Dept. of Administration requested a revision. The regulation has been amended and sent for review but has not been returned to the Board for public hearing.

# K.A.R. 68-7-19 Transfer by Interns

This regulation has legal problems and was not approved by the Attorney General's Office. The regulation will be on the next agenda so that the Board counsel can make suggestions as what the Board's options are.

## K.A.R. 68-13-1 through K.A.R. 68-13-5 Compounding Regulations.

The regulations are under review of the Dept. of Administration and the Attorney General's Office and have not been sent to the Board for public hearing.

#### BOARD REPORTS

**Mike Coast, R.Ph.** discussed Internet issues with the Board staff. He requested that the Board ask at least one wholesale distributor to provide the ten highest customers of a high risk formulary in order to determine whether Internet activity is occurring.

**Merlin McFarland, R.Ph.** Merlin reported that he was continuing to work on classifications of pharmacies. He has met with Frank Whitchurch on several occasions. Certain things do apply universally to all pharmacies but we do need some specifics for nuclear pharmacies, etc. Merlin stated that he would continue to work on this issue with Frank even after he goes off the Board.

Merlin also provided that the Board inspectors need to make sure that anyone who is using an electronic 222 form should be able to show the inspector that they have backed it up, that they have the capability to reconcile, and can print documentation.

**JoAnne Gilstrap, R.Ph.** asked the Board staff to check with the Board of Healing Arts to see if they are doing anything related to Internet Prescribing and the patient/physician relationship.

JoAnne asked for clarification from the Board regarding CII prescriptions that are filled and not picked up by the patient. The product is usually returned to stock but the question was whether the prescription was considered canceled? The Board discussed this and stated that the prescription could be put on hold for up to 6 months and filled if the patient eventually came in. One way of handling it would be to void the transaction in the computer and put it into a hard copy file. Therefore, the CII could be filled at a later date if it was not picked up when originally filled.

JoAnne wanted the minutes to reflect the hard work of Max Heidrick, R.Ph. as President this past year and for his service to the Board of Pharmacy. It is very much appreciated by all members of the Board.

**Shirley Arck, Pharm.D.** advised the Board that she had contacted Barry Sarvis about serving on a task force for the Board of Pharmacy. He was interested but would need additional information regarding the specifics. Board staff will contact Mr. Sarvis with the information.

Randy Forbes reported that he had been requested to ask the Board for something in writing that sets out the duties of pharmacy technicians. The Board discussed this issue and clarified that they cannot make an all inclusive list since the statute states that the pharmacy technician may do any function that is non-judgmental in nature. They did review other states statutes and regulations previously and there are very few states that have a list of duties since that would be difficult to do. The Board will try to provide some type of list that would be helpful.

**Debra Billingsley** advised the Board that she would need to know who could attend the NABP Spring Meeting on May 19-22. There will be training on inspecting compounding pharmacies and the Board will send at least one inspector. Mike Coast will be the Board's delegate.

Kansas will be hosting the District VI Meeting this fall. Gene Hotchkiss is assisting the Board in putting something together. The Board needs to notify NABP of an exact date and location as soon as possible.

**ADJOURNMENT:** The Board adjourned at 11:30 a.m.